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EXAMINER

COLELLO, ERIN L

ART UNIT

PAPER NUMBER

3734

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/801,906	Applicant(s) MELKENT ET AL.	
	Examiner ERIN COLELLO	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-17,19,39-45 and 47-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-17,19,39-45 and 47-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>November 23, 2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicant's amendment filed November 23, 2009. Claims 1, 3-17, 19, 39-45, 47-54 and new claims 55-57 are pending and an action on the merits is as follows.

Applicant's arguments with respect to claims 1, 3-17, 19, 39-45, 47-54 have been considered but are moot in view of the new ground of rejection.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 44 recites the limitation "the at least one trackable marker" in lines 1-2 of claim 44. There is insufficient antecedent basis for this limitation in the claim.

Specification

4. The amendment filed November 23, 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The attempt to incorporate subject matter into this application by reference to U.S. Patent

09/795,126 and U.S. Provisional 60/186,200 is ineffective because the root words "incorporate" and/or "reference" were not included in the original disclosure.

An incorporation by reference statement added after an application's filing date is not effective because no new matter can be added to an application after its filing date (see 35 U.S.C. 132(a)). If an incorporation by reference statement is included in an amendment to the specification to add a benefit claim after the filing date of the application, the amendment would not be proper. When a benefit claim is submitted after the filing of an application, the reference to the prior application cannot include an incorporation by reference statement of the prior application unless an incorporation by reference statement of the prior application was presented upon filing of the application. See *Dart Indus. v. Banner*, 636 F.2d 684, 207 USPQ 273 (C.A.D.C. 1980).

Applicant is required to cancel the new matter in the reply to this Office Action.

Terminal Disclaimer

5. The terminal disclaimer filed on December 10, 2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6,725,080 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3734

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 39, 44-45 and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by **Smith et al. (CA 2,201,877)**.

Regarding claim 39, Smith discloses an apparatus for the placement of surgical implements, comprising: a first fixture having a first configuration (Ref 354, 350) defined by a fixed attachment point (Ref 332, 360) and a first frame coupling region (Ref 360); a second fixture (Ref 300) different from the first fixture and having a second configuration (Ref 350, 354) defined by a fixed attachment point (Ref 332) and a second frame coupling region (Ref 328; Page 35, lines 33-36; Page 36, lines 1-7); a plurality of cannulas (Ref 364, 304, 334) operable to be coupled to at least one of the first fixture or the second fixture via the respective plurality of attachment points (Ref 354, 350, 300); and a trackable marker (Ref 316) associated with all of the plurality of cannulas (Ref 364, 304, 334), the trackable marker mounted on a single frame (Ref 302), the single frame operable to be selectively coupled to the first frame coupling region of the first fixture (Figures 13D-E) or the second frame coupling region of the second fixture (Figures 13A-C), wherein upon coupling the plurality of cannulas (Ref 364, 304, 334) with the first fixture or the second fixture (Ref 354, 350, 300), the plurality of cannulas are positioned in at least one of the first configuration or the second configuration (Figures 13A-E), and the trackable marker is detectable by an instrument location system to detect the position of the plurality of cannulas relative to an anatomy in real-time (Page 4, lines 32-35; Page 5, lines 1-18; Page 6, lines 14-19; Page 7, lines 1-13; Page 9, lines 1-20; Page 10, lines 1-31).

Regarding claim 44, Smith discloses that the at least one trackable marker is selected from a group comprising a reflective marker, a light emitting marker, an acoustic marker, a magnetic marker, an optical marker, an electromagnetic marker, a radiological marker, and combinations thereof (Ref 316; Page 31, lines 16-34).

Regarding claim 45, Smith discloses that the surgical implement is at least one of a surgical tool or an implant (Page 39, lines 21-30).

Regarding claim 56, Smith discloses that the first frame coupling region (Ref 360) and the second frame coupling region (Ref 238) are substantially similar (Figures 13A-E; wherein both of the frame coupling regions are around the center of the frame (302)) and operable to both couple with the frame (Ref 302) individually (Figures 13A-C; Figures 13D-E).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1, 3-8, 10-13, 15-17, 40-43, 47-50, and 52-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Smith et al. (CA 2,201,877)**.

Regarding claim 1, Smith discloses an apparatus for the placement of surgical implements, comprising: a fixture (REF 354, 350) that defines a fixed attachment point (Ref 332; 360); a cannula (Ref 364) coupled to the fixture with the cannula coupled to a

Art Unit: 3734

respective attachment point (Ref 354, 350, 360); at least one trackable marker associated with the cannula (Ref 316), the at least one trackable marker mounted on a frame (Ref 302) that is coupled to the fixture to enable an instrument location system to detect a position of the cannula throughout a surgical procedure without obstructing the cannula during the procedure (Page 9, lines 1-20; Page 10, lines -31; Page 36, lines 22-36; Page 37, Lines 1-30); and a surgical implement receiver (Ref 362) provided on the fixture for receiving surgical implements (Page 36, Lines 22-36; Page 37 lines 1-30; Page 39, lines 25-27), the receiver being substantially coaxially aligned with a respective cannula to enable a surgical implement to pass through a respective receiver and cannula (Page 36, Lines 22-36; Page 37 lines 1-30; Page 39, lines 25-27; wherein 362 and 364 are coaxially aligned).

Smith discloses all of the claimed limitations above but fails to explicitly disclose that there are a plurality of attachment points, a plurality of cannulas and a plurality of surgical implement receivers.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a plurality of attachment points, a plurality of cannulas and a plurality of surgical implement receivers, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v Bemis Co.*, 193 USPQ 8.

Regarding claim 3, Smith discloses a peripheral structure (Ref 356), coupled to the fixture (Ref 354, 350), for maneuvering to move the fixture and thereby maneuver the cannula during a surgical procedure to place the surgical implements (Ref 356).

Regarding claim 4, Smith discloses that the surgical receivers is a flange configured to receive the surgical implements (Ref 362).

Regarding claims 5 and 42, Smith discloses all of the claimed limitations above but fails to explicitly disclose that at least one of the plurality of cannulas is individually adjustable to vary its length.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have a cannula that can vary its length in order to allow the cannula to accommodate to the varying surgical location.

Regarding claims 6-8, 41 and 43, Smith discloses all of the claimed limitations above including that the cannula can be at an angle relative to the fixture but fails to explicitly disclose that at least one of the plurality of cannulas is individually adjustable to vary an angular position of at least one of the plurality of cannulas relative to the fixture and the peripheral structure; wherein the angular position can be an azimuth angular position measured in a horizontal reference plane associated with the fixture or it can be an elevation angular position measured in a vertical reference plane associated with the fixture.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have a cannula that can vary its angular position in order to allow the cannula to adjust to align relative to the varying surgical location.

Regarding claim 10, Smith discloses that the peripheral structure is a pistol grip configured graspable handle (Ref 356).

Regarding claim 11, Smith discloses that the peripheral structure is machine operated (Page 20, lines 32-36; Page 21, lines 1-15; wherein an instrument can be controlled using robotics).

Regarding claims 12 and 47, Smith discloses all of the claimed limitations above but fails to explicitly disclose a plurality of interchangeable frames, at least two of the frames having a different type of trackable marker.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use different frames with different markers, since different markers would allow a surgeon to visualize different areas or instruments in a different manner, such as with the use of an ultrasound or an MRI.

Regarding claim 13, Smith discloses that the surgical implement is at least one of a surgical tool or an implant (Page 39, lines 21-30).

Regarding claim 15, Smith discloses all of the claimed limitations above but fails to explicitly disclose that at least one of the plurality of cannulas is individually adjustable to vary at least one of its inner diameter or outer diameter.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have a cannula that can vary in diameter in order to allow different size instruments to enter the lumen.

Regarding claim 16, Smith discloses all of the claimed limitations above but fails to explicitly disclose that at least one of the plurality of cannulas includes a serrated structure for gripping portions of a patient's anatomy.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a serrated cannula with the device of Smith in order to allow the cannula to grip to the sides of the body member and help secure the cannula in place.

Regarding claim 17, Smith discloses that the at least one trackable marker is selected from a group comprising a reflective marker, a light emitting marker, an acoustic marker, a magnetic marker, an optical marker, an electromagnetic marker, a radiological marker, and combinations thereof (Ref 316; Page 31, lines 16-34).

Regarding claim 40, Smith discloses all of the claimed limitations above but fails to explicitly disclose a plurality of cannulas in the first configuration

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a plurality of parallel cannulas, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v Bemis Co.*, 193 USPQ 8.

Regarding claims 48-49, Smith discloses an apparatus for the placement of surgical implements, comprising: a fixture (Ref 350, 354) that includes a pistol grip configured grasping handle (Ref 356) and a fixed attachment point (Ref 332, 360); a cannula (Ref 364) coupled to a respective attachment point (Ref 360, 332) of the fixture (Ref 350, 354) so that manipulation of the pistol grip configured grasping handle maneuvers the cannula simultaneously (Ref 356); a plurality of trackable markers coupled to the fixture (Ref 316); a surgical navigation system that tracks the plurality of trackable markers to determine a position of each of the plurality of cannulas relative to

Art Unit: 3734

an anatomy Page 29, Lines 15-30; Page 4, lines 32-35; Page 5, lines 1-18; Page 7, lines 1-13; Page 9, lines 1-20; Page 10, lines 1-31); and a display that displays an icon representative of the position of the cannula superimposed onto an image of the anatomy (Ref 124; Page 4, lines 32-35; Page 9, lines 1-20; Page 10, lines 1-31); a surgical implement receiver (Ref 362) provided on the fixture for receiving surgical implements (Page 39, lines 21-30), the receivers being substantially coaxially aligned with a respective cannulas (Page 36, Lines 22-36; Page 37 lines 1-30; Page 39, lines 25-27; wherein 362 and 364 are coaxially aligned). .

Smith discloses all of the claimed limitations above but fails to explicitly disclose that there are a plurality of attachment points, a plurality of cannulas and a plurality of surgical implement receivers.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a plurality of attachment points, a plurality of cannulas and a plurality of surgical implement receivers, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v Bemis Co.*, 193 USPQ 8.

Smith fails to explicitly disclose that the cannula is independently adjustable relative to the fixture.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have a cannula that can be adjustable to vary its angular position in order to allow the cannula to adjust to align relative to the varying surgical location.

Regarding claim 50, Smith discloses an imaging device operable to acquire one or more images of the anatomy (Page 4, lines 32-35; Page 5, lines 1-18; Page 7, lines 1-13; Page 9, lines 1-20; page 10, lines 1-31).

Regarding claim 52, Smith discloses a display that displays an icon representative of the position of each of the plurality of cannulas overlaid onto an image of the anatomy (Ref 124; Page 4, lines 32-35; Page 5, lines 1-18; Page 7, lines 1-13; Page 9, lines 1-20; Page 10, lines 1-31).

Regarding claim 53, Smith discloses that the display (Ref 124) also displays a plurality of icons that each represent a projected trajectory for each of the plurality of cannulas superimposed onto the image of the anatomy (Page 4, lines 32-35; Page 5, lines 1-18; Page 7, lines 1-13; Page 9, lines 1-20; Page 10, lines 1-31).

Regarding claim 54, Smith discloses that the peripheral structure is fixed relative to the attachment point (Ref 356; 332, 360).

Regarding claim 55, Smith discloses that the pistol grip configured grasping handle includes an elongated member, operable to be grasped by a hand of a user; wherein the elongated member extends at an angle of less than 180 degrees relative to a long axis of any of the plurality of the cannulas coupled to the fixture (Ref 356; wherein the elongated member is at an angle of zero degrees).

10. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Smith et al. (CA 2,201,877)** in view of **Bramlet et al. (US 5,649,946)**.

Regarding claim 14, Smith discloses all of the claimed limitations above but fails to explicitly disclose that at least one of the plurality of cannulas can be interchanged with a cannula having at least one of a different inner diameter or outer diameter.

However, Bramlet teaches that it is well known in the art to interchange medical tools having differing configurations to be releasably attached to a handle in order to add versatility to the medical instrument (Column 20, lines 5-22; Column 21, lines 9-14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Smith to allow a variety of cannulas with differing configurations to be interchanged in order to add versatility to the device.

11. Claims 9 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Smith et al. (CA 2,201,877)** in view of **Warner et al. (US 5,871,487)**.

Regarding claims 9 and 51, Smith discloses that the frame (Ref 302) can be used with a variety of fixtures (Page 37, lines 31-36; Page 35, lines 1-32, Page 36, lines 22-36; Page 37, lines 1-30) and that the fixture (Ref 350) is attached to the handle (Page 36, lines 33-34) but Smith fails to explicitly disclose that the fixture can be interchangeable

However, Warner teaches that it is well known in the art to interchange a fixture with other fixtures with slightly different means suitable for holding different surgical instruments, such as electrodes, biopsy instruments etc (Column 5, lines 34-40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Smith to allow a variety of fixtures with differing configurations to be interchanged in order to add versatility to the device.

12. Claims 19 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Smith et al. (CA 2,201,877)** in view of **Jacobson (US 5,665,095)**.

Regarding claims 19 and 57, Smith discloses that the frame (Ref 302) is removably coupled relative to the fixture (Ref 350, 354, 360, and 332) but fails to explicitly disclose coupling the frame to the fixture using a dove-tail connection.

However, Jacobson teaches a dove-tail connection for placing a frame assembly (Ref 34), therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the connection of Smith with a dove-tail connection in order to couple a frame assembly in alignment with a structure.

Response to Arguments

Applicant's arguments with respect to claims 1, 3-17, 19, 39-45, 47-54 have been considered but are moot in view of the new ground of rejection.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

Art Unit: 3734

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIN COLELLO whose telephone number is (571)270-3212. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. C./

Examiner, Art Unit 3734

Application/Control Number: 10/801,906

Page 15

Art Unit: 3734

/TODD E. MANAHAN/

Supervisory Patent Examiner, Art Unit 3734